

IN THE CLAIMS

1. **(Cancelled)** A method for delivering a desired amount of a drug to a treatment site of a subject, the method comprising:
causing a quantity of drug to exit from a drug reservoir of a drug delivery device in a direction toward a treatment site; and
diverting a portion of the quantity of drug exiting the drug delivery device away from the treatment site such that said diverted portion does not reach the treatment site;
wherein said diverting results in delivery of a desired amount of drug to the treatment site.
2. **(Cancelled)** The method of claim 1, wherein the treatment site is a biologically confined treatment site and the diverted drug is diverted into a systemic site within the subject.
3. **(Cancelled)** The method of claim 1, wherein the diverted drug is collected into a waste reservoir.
4. **(Cancelled)** The method of claim 1, wherein the desired amount of drug is delivered to the treatment site by varying the amount of drug delivered to the treatment site relative to the amount of drug diverted from the drug delivery device.
5. **(Cancelled)** The method of claim 1, wherein said diverting is by intermittent disruption of flow of drug exiting the drug delivery device.
6. **(Cancelled)** A flow regulator comprising:
a delivery conduit comprising a proximal delivery inlet, a distal delivery outlet, and a delivery lumen extending between the proximal delivery inlet and the distal delivery outlet, the delivery conduit lumen defining a delivery pathway; and

a diversion element positioned so as to facilitate diversion of flow of drug in a direction away from the delivery pathway.

7. **(Cancelled)** The flow regulator of claim 6, wherein the diversion element is manually adjustable.

8. **(Cancelled)** The flow regulator of claim 6, wherein the diversion element is remotely adjustable.

9. **(Cancelled)** The flow regulator of claim 6, wherein the diversion element is a valve.

10. **(Cancelled)** The flow regulator of claim 9, wherein the valve is a compression valve for compressing against a deformable wall of the delivery conduit at a site distal to the diversion inlet.

11. **(Cancelled)** The flow regulator of claim 9, wherein the valve is a rotatable valve.

12. **(Cancelled)** The flow regulator of claim 9, wherein the valve is a solenoid.

13. **(Cancelled)** The flow regulator of claim 6, wherein the flow regulator further comprises:

a diversion conduit comprising a diversion inlet, a diversion outlet, and a diversion lumen extending between the diversion inlet and diversion outlet, the diversion conduit lumen defining a diversion pathway;

wherein drug diverted by the diversion element flows into the diversion pathway defined by the diversion conduit.

14. **(Cancelled)** The flow regulator of claim 13, wherein the delivery conduit and the diversion conduit intersect in a substantially T-shaped configuration.

15. **(Cancelled)** The flow regulator of claim 13, wherein the delivery conduit and the diversion conduit intersect in a substantially Y-shaped configuration.
16. **(Cancelled)** The flow regulator of claim 13, wherein the delivery conduit and the diversion conduit intersect in a substantially U-shaped configuration.
17. **(Cancelled)** The flow regulator of claim 13, wherein the diversion conduit is in fluid communication with a waste reservoir for receiving drug from the diversion outlet.
18. **(Cancelled)** The flow regulator of claim 17, wherein the waste reservoir comprises a self-sealing septum.
19. **(Cancelled)** The flow regulator of claim 6, wherein the delivery conduit comprises an attachment element for attaching a drug delivery device for delivery of drug into the proximal delivery inlet.
20. **(Cancelled)** The flow regulator of claim 6, wherein the delivery conduit comprises a valve at a delivery conduit distal end.
21. **(Cancelled)** The flow regulator of claim 6, wherein the flow regulator is contained within a housing element.
22. **(Cancelled)** The flow regulator of claim 14, wherein the housing element comprises a biocompatible, implantable material.
23. **(Cancelled)** The flow regulator of claim 6, wherein the flow regulator is attached to a drug delivery catheter at a delivery conduit distal end to provide for flow of drug from the delivery pathway, out the distal delivery outlet, and into a lumen of the drug delivery catheter.

24. **(Withdrawn)** A drug delivery system comprising;
the flow regulator of claim 6; and
a drug delivery device;
wherein the drug delivery device is attached to the flow regulator to facilitate delivery of a drug from the drug delivery device, through the delivery conduit lumen, and out the distal delivery outlet.

25. **(Withdrawn)** The drug delivery system of claim 24, wherein the flow regulator is detachably attached to the drug delivery device.

26. **(Withdrawn)** The drug delivery system of claim 24, wherein the drug delivery device is a convective drug delivery device.

27. **(Withdrawn)** The drug delivery system of claim 24, wherein the drug delivery device is a diffusive drug delivery device.

28. **(Withdrawn)** The drug delivery system of claim 24, wherein the flow regulator further comprises:

a diversion conduit comprising a diversion inlet, a diversion outlet, and a diversion lumen extending between the diversion inlet and diversion outlet, the diversion conduit lumen defining a diversion pathway;

wherein drug diverted by the diversion element flows into the diversion pathway defined by the diversion conduit.

29. **(Withdrawn)** The drug delivery system of claim 24, wherein the drug delivery device is implantable.

30. **(Withdrawn)** A drug delivery catheter comprising a catheter body defining a proximal opening, a distal opening, and a catheter lumen extending between the proximal and distal openings, the catheter further comprising a flow regulator according to claim 6,

wherein the catheter lumen and the flow regulator delivery lumen are in fluid communication.

31. **(Withdrawn)** The drug delivery catheter of claim 26, wherein the flow regulator delivery conduit is continuous and integral to the catheter body.

32. **(Withdrawn)** The drug delivery catheter of claim 26, wherein the flow regulator is positioned at a proximal portion of the catheter.

33. **(Cancelled)** A method of administering drug to a treatment site in a subject, the method comprising:

implanting at least the distal end of the flow regulator delivery conduit of the flow regulator of claim 1 at a treatment site within a subject; and

delivering drug from a drug delivery device, through the drug delivery pathway of the flow regulator, and to the treatment site;

wherein the drug is administered to the treatment site in the subject.

34. **(Cancelled)** The method of claim 33, wherein the delivery conduit lumen is suitable for delivery of the drug at a low volume rate.

35. **(Cancelled)** The method of claim 33, wherein the flow regulator drug delivery conduit provides for delivery of drug to at least two treatment sites.

36. **(Cancelled)** The method of claim 33, wherein the treatment site is subcutaneous, percutaneous, intravenous, intramuscular, intra-arterial, intravascular, intraperitoneal, intraspinal, epidural, intrathecal, intracranial, intracardial, peritumoral, or intratumoral.

37. **(Cancelled)** The method of claim 33, wherein the treatment site is a site within a kidney, liver, pancreas, heart, lung, eye, ear, lymph node, breast, prostate, ovary, testicle, thyroid, spleen, central nervous system, skeletal muscle, bone, lymph vessel, artery, arteriole, capillary bed, blood vessel, vein, peripheral nervous system, digestive

system, gastrointestinal tract, urinary bladder, gall bladder, adrenal gland, adipose tissue, parathyroid gland, uterus, fallopian tube, skin, tumorous growth, autologous graft, synthetic graft, or site of microbial infection.

38. **(Cancelled)** A method of controlling an amount of drug administered to a treatment site in a subject, the method comprising:

introducing a drug into the flow regulator proximal delivery inlet of the drug delivery system of claim 1, said introducing resulting in drug flowing through the drug delivery pathway and to a treatment site in a subject at which a distal end of the drug delivery conduit is implanted; and

adjusting the diversion element of the flow regulator to divert drug from the drug delivery pathway;

wherein said adjusting alters the amount of drug that is delivered to the treatment site in the subject.

39. **(Cancelled)** The method of claim 38, wherein the drug delivery device is a constant rate drug delivery device.

40. **(Cancelled)** The method of claim 38, where drug diverted from the drug delivery pathway is delivered to the subject systemically.

41. **(Cancelled)** The method of claim 38, wherein the flow regulator comprises a waste reservoir for receiving drug diverted from the delivery pathway.

42. **(Cancelled)** The method of claim 38, wherein the distal end of the drug delivery conduit is attached to a drug delivery catheter to provide for extension of the drug delivery pathway to a catheter delivery outlet at the catheter distal end, wherein at least the catheter distal end is implanted at the treatment site.

43. **(Cancelled)** The method of claim 42, wherein the catheter is adapted for delivery of drug to two treatment sites.

44. **(Cancelled)** The method of claim 38, wherein the treatment site is subcutaneous, percutaneous, intravenous, intrathecal, intramuscular, intra-arterial, intravascular, intraperitoneal, intraspinal, epidural, intracranial, intracardial, peritumoral, or intratumoral.

45. **(Cancelled)** The method of claim 38, wherein the treatment site is a site within a kidney, liver, pancreas, heart, lung, eye, ear, lymph node, breast, prostate, ovary, testicle, thyroid, spleen, central nervous system, skeletal muscle, bone, lymph vessel, artery, arteriole, capillary bed, blood vessel, vein, peripheral nervous system, digestive system, gastrointestinal tract, urinary bladder, gall bladder, adrenal gland, adipose tissue, parathyroid gland, uterus, fallopian tube, skin, tumorous growth, autologous graft, synthetic graft, or site of microbial infection.

46. **(Cancelled)** The method of claim 38, wherein the diversion element is adjusted for a first time period so as to facilitate flow through the delivery conduit, and for a second time period so as to decrease flow through the diversion conduit, wherein varying the length of the first and second time periods results in alteration in the amount of drug delivery to the treatment site.

47. **(Cancelled)** The method of claim 38, wherein the flow regulator further comprises:

a diversion conduit comprising a diversion inlet, a diversion outlet, and a diversion lumen extending between the diversion inlet and diversion outlet, the diversion conduit lumen defining a diversion pathway;

wherein drug diverted by the diversion element flows into the diversion pathway defined by the diversion conduit.

48. **(Cancelled)** The method of claim 47, wherein the diversion element is adjusted so that the delivery conduit and the diversion conduit are each partially open.

49. **(New)** A flow regulator for regulating flow of a drug to a treatment site within the body of a subject, the flow regulator comprising:

a drug reservoir,

a delivery conduit operably connected to the drug reservoir,

a diversion conduit operably connected either to the drug reservoir or to the delivery conduit,

a means for diverting the flow of drug from the delivery conduit to the diversion conduit,

wherein the delivery conduit terminates at or near the treatment site, and wherein the diversion conduit terminates at a site other than a treatment site and away from the treatment site.

50. **(New)** The flow regulator of claim 49, wherein the diversion conduit terminates at a site within the body of the subject.

51. **(New)** The flow regulator of claim 49, wherein the a means for diverting the flow of drug comprises an adjustable valve.

52. **(New)** The flow regulator of claim 51, wherein the valve is adjustable remotely.

53. **(New)** The flow regulator of claim 52, wherein the flow regulator is fully implantable within the body of the subject.

54. **(New)** The flow regulator of claim 51, wherein the valve comprises a rotatable valve.

55. **(New)** The flow regulator of claim 51, wherein the valve comprises a solenoid.

56. (New) The flow regulator of claim 49, wherein the delivery conduit and the diversion conduit intersect in a substantially T-shaped configuration.

57. (New) The flow regulator of claim 49, further comprising a waste reservoir in fluid communication with the diversion conduit.

58. (New) The flow regulator of claim 57, wherein the waste reservoir comprises a self-sealing septum.

59. (New) The flow regulator of claim 49, wherein the delivery conduit comprises an attachment element for attaching a drug delivery device for delivery of drug into the delivery conduit.

60. (New) The flow regulator of claim 49, wherein the treatment site is selected from the group consisting of: a subcutaneous, percutaneous, intravenous, intramuscular, intra-arterial, intravascular, intraperitoneal, intraspinal, epidural, intrathecal, intracranial, intracardial, peritumoral, and an intratumoral treatment site.

61. (New) The flow regulator of claim 49, wherein the treatment site is selected from the group consisting of: kidney, liver, pancreas, heart, lung, eye, ear, lymph node, breast, prostate, ovary, testicle, thyroid, spleen, central nervous system, skeletal muscle, bone, lymph vessel, artery, arteriole, capillary bed, blood vessel, vein, peripheral nervous system, digestive system, gastrointestinal tract, urinary bladder, gall bladder, adrenal gland, adipose tissue, parathyroid gland, uterus, fallopian tube, skin, tumor, graft, synthetic graft, and site of microbial infection.

62. (New) The flow regulator of claim 49 wherein the means for diverting the flow of drug is programmable such that drug is delivered at a variable but predictable rate over time.